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Variation in Institutional Pharmaceutical Formularies

by

Joseph James Gebran 

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of

Master of Public Health

in

Health Policy Research

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The undersigned certify that they have read, and recommend to the Faculty of Graduate Studies and Research for acceptance, a thesis entitled "Variation in Institutional Pharmaceutical Formularies" submitted by Joseph James Gebran in partial fulfillment of the requirements for the degree of Master of Public Health in Health Policy Research.

Abstract

Formulary decision making within institutions (hospitals, inpatient health care delivery organizations) is a complex activity. The objectives of this study were: 1) to identify the factors that influence Pharmacy & Therapeutics (P&T) Committee members in their decision making, and; 2) examine the level of agreement between Regional Health Authority (RHA) formularies.

It was found that at least 63 factors, which were consolidated into 11 groups, influence P&T Committee members in their formulary decision making.

It was also found that there is a high level (85%) of raw agreement between RHA formulary decisions taken. Using Kappa to correct for chance agreement, it was found that there was only "Slight" agreement (Kappa = 0.15).

Numerous policy implications for managing formulary decision making within RHAs are presented.

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I – Introduction

Decision making in health care has undergone tremendous transformation over the past fifteen years.

Whereas physicians, managers, and policy makers once acted mainly using their best judgement and knowledge, the expectation is now that those designing and directing health services, and those delivering care to patients, use research-generated evidence to inform their decisions (Lomas, 2000).

Simultaneous with these changing expectations, numerous health research organizations have been established in Canada (Menon and Topfer, 2000). This has also occurred internationally (Cookson and Maynard, 2000).

The impact of the research-generated evidence on decision making is only partially understood as this effect has not yet been systematically evaluated (Menon, 2000). It is thought that research-generated evidence is not informing decision making to the extent it should. This is partly due to a significant gap that exists between health care researchers and decision makers, resulting in research-generated evidence being discounted in decision making processes (Lomas, 2000).

Bridging the gap between health care researchers and decision makers is a significant challenge (Drummond and Weatherly, 2000). The Government of Canada recognized this gap and created the Canadian Health Services Research Foundation to help resolve the conflicts and build bridging mechanisms between the two groups. Each year, the Foundation budgets up to CDN $10 M on bridging activities (Lomas, 2000).

As a result of the changing paradigm and the varying utilization of research-generated evidence in decision making, it was thought that decisions taken by health care organizations may vary. By examining the pharmaceutical selection component of health care, examples of such differences could be obtained and explained.

The process of reviewing and approving pharmaceutical products for use within an institution usually occurs through pharmaceutical formulary committees. Pharmaceutical formularies have been used as a method of reducing the costs and improving the use of pharmaceuticals in publicly funded health institutions and prescription drug programs (Jacobs and Bachynsky, 1999).

At the provincial level in Canada, differences have been observed in the length of time to review products and in the decisions taken by Canadian provinces regarding the listing of new pharmaceutical products as a benefit (Applied Management, 1998). These differences occur even though the stated listing criteria are similar in a number of jurisdictions (Anis, Daphne, and Xiao-Hua, 2001).

The differences in decisions taken are due to numerous factors. The maintenance of formularies is a complex activity that must reflect competing considerations, inputs and incentives, one of which is the role of economic evaluations in the decision making process (Johnson and Friesen, 1998). As a result, it is possible that among similar

institutions there would be differences in the products that are included on their respective formularies. It is also possible that the policies governing new product listings within health care organizations may not be appropriately reflected in actual decision-making practice.

In Alberta recently, regionalization of health care has occurred with the creation of 17 regional health authorities (RHA). Each of these is responsible for delivering care in their region. Each has a formulary decision making process. It was expected that there were differences, although the extent of the differences were unknown, among these RHAs insofar as the pharmaceuticals that are available on their formularies were concerned, even after taking into consideration that some programs may be offered only in one or two RHAs.

In a formulary process review initiative that occurred between RHAs and government, officials indicated that varying formulary decisions do occur (Gebran, 1998). During these initiatives, officials representing Alberta Health and Wellness and some RHAs indicated that they faced challenges of:

- operating in isolation of one another,
- overburdening experts with formulary review activities,
- reaching differing decisions, sometimes inappropriately, and
- not having optimal health system performance due to fragmented approaches.

The group further articulated a desire to create more harmonization in the formulary decision making processes within their RHAs and government, including multi-jurisdictional drug decision making groups, deliberate processes for sharing information and analyses on drugs among formulary review bodies, and developing a "best practice" process for formulary decision making in Alberta.

Based on evidence of variations in provincial formulary decisions and potential for improving RHA formulary decision-making processes in Alberta, an investigation into RHA formulary decision-making seemed warranted.

The objectives of the project were to:

- examine the level of agreement between RHA formularies. To do this, two activities were undertaken:
  - identification of the formulary listing status of 86 pharmaceutical products approved for sale in Canada in 1996, 1997, and 1998 in each of the 17 RHA formularies.
  - quantification of the nature and extent of variation among the 17 RHA formularies.
- identify the factors that influence Pharmacy & Therapeutics (P&T) Committee members in their decision making.

II – Methods

The methodology of this study drew on those utilized in two independent research projects, Anis et al., 2001, and by Gregoire et al., submitted, that assessed variability in decision making among provincial formularies in Canada.

A. Literature Review

The purpose of the literature review was to identify, using the published experiences of institutional pharmaceutical decision making bodies, the factors that contribute to pharmaceutical listing decisions (formularies).

To accomplish this, a comprehensive literature review was undertaken with the assistance of a health information specialist. Direction was also sought from a key informant panel.

Contained herein are the search strategy, information sources, citation refinement criteria, and review results.

Search Strategy & Information Sources

A comprehensive literature search was conducted using Dialog OneSearch® on the following databases:

-MEDLINE
-HealthSTAR
-EMBASE
-CBCA Fulltext
-International Pharmaceutical Abstracts
-Social SciSearch
-SciSearch
-NTIS
-Dissertation Abstracts Online

The initial search was conducted in August 1999. This was restricted to literature published from 1970 to date. An updated search, using the same search strategy, was subsequently run covering the period January 1999 to May 2000. The search was further restricted to English language publications only.

Keywords used in the literature search were limited to those appearing in the title (ti) or descriptor (de) fields as shown below. (Note: ? denotes word truncation.)

decision(w)making or decision? or adopt? or list? or approval? or acquisition

AND

formularies or formulary or insurance(w)coverage or insurance(w)pharmaceutical or health(w)policy or pharmacy(1w)therapeutics(w)committee? or managed(w)care or

hospital or hospitals or health(w)care or healthcare or drug(w)benefit? or drug(w)evaluation

AND

drug? or pharmaceutical? or formular?

NOT

(physician or clinician)/ti

Duplicate citations were removed, leaving a total of 676 references in the original search, and 379 in the update search for a total of 1055 citations.

Citation Refinement Criteria

The citations from the search results were further refined to include:

- citations with a hospital, health authority, or institutional focus (as determined from citation title or abstract). This included HMOs and the US military but excluded all citations referring to governmental or individual patient foci.
- only drug coverage decisions. Articles concerning medical device decisions, clinical decision making (ie. appropriate treatment regimens), or mechanisms related to supporting or enhancing clincial decision making (ie. Clinical Practice Guidelines, expert systems) were excluded.
- published experiences with processes for decision making. Articles outlining a theoretical approach to decision making were excluded.

The 676 citations were reviewed using these criteria. 37 of these were included in the literature review (references #1 to 37 in the Bibliography). A copy of the article of each of the 37 citations was subsequently obtained.

Review Results

Each article was abstracted for three types of information: (i) factors that influenced the formulary decision making process, (ii) a quantified measurement or comparison of the degree of agreement in drug listings among formularies, and (iii) factors that explained the degree of agreement or difference among institutional formularies.

(i) Factors that influence formulary decision making. 56 factors that influence the formulary decision making process in institutions were identified in the literature (Table #I).

TABLE I – Factors identified in the literature that influence the formulary decision making process

Factors	Article where factor was cited
Cost (acquisition, daily)	2,4,5,6,7,10,13,14,16,17,18,19,21,22,23,27,28,29, 32,33,35,37
Clinical efficacy (published, unpublished)	1,2,3,4,5,6,9,10,13,14,17,21,22,27,28,29,34,35
Adverse effects	2,6,7,13,14,16,17,19,22,23,27,29,32,34
Safety (published)	1,3,5,9,10,13,14,18,21,33
Pharmacokinetics	2,13,16,19,22,23,27,32
Dosage frequency/forms	2,10,14,17,23,27,32
Effectiveness	3,6,9,13,14,18
Indications for use	6,13,14,16,23,35
Patient acceptance	10,14,18,21,33,37
Patient outcomes (health status, health-related quality of life)	3,4,13,24,29,31
Sponsor (i.e. internal champion)	6,14,32,34,35,37
Alternative available (generic)	6,13,14,33,34
Therapeutic advantage	7,14,22,32,35
Drug interactions	2,14,17,27
Personal experience with manufacturer/representative	2,10,14,27
Comparative data	5,29,32
Documentation	2,23,27
Drug budget (i.e. impact on total drug budget)	6,9,11
Ease of use	10,14,37
Estimated usage of drug	6,14,35
Past experience with manufacturer	2,14,27
Pharmacist consent to new drug being used	8,31,32
Physician consensus (other consensus)	20,26,31
Preparation requirements	10,21,37
Product stability	10,16,19
Chart review by pharmacist on how drug is being used	12,37
Customer service of supplier	14,37
Data generated at local/organizational level	1,25
Drug administration	15,37
Interaction amongst members of P&T committee	30,31
Management structure	9,28
Observed adverse effects/negative experience with drug	2,27
Observed/perceived benefit of drug	2,27
Organization goals/context	9,25
Past prescribing volume of physicians	14,37
Personal financial motivation	2,27
Years drug in use (product life span, obsolescence)	17,22
Accountability for claims	9
Care giver opinion	33
Case mix that drug can be used for	6
Degree of risk	28
Drug strengths	15
Drug Utilization Reviews	33
Ethical review	11
Federal Drug Administration approval	33
Flavour	10
Hospital size	31
Inclusion of formulary body in data generation and analysis	1
Internal ability to evaluate studies	25
Literature review	33
Objectivity/credibility	25
Personal opinion	4
Physician convenience	21
Product storage issues	10
Sources of information	31
Toxicity	23

For an article to be included in the table, specific mention of the factor must have been made explicitly in the body of the text. No tabulations were made where a factor identified as influencing the decision making process could only be derived by combining other factors (i.e. Cost Effectiveness Analysis) as there was no way to ascertain whether the factor in question was a consistent definition among the authors of the various papers.

(ii) Degree of agreement on formularies between institutions. No articles were found that described any comparison of the individual drugs listed on formularies among organizations.

(iii) Factors that explain the degree of agreement. No articles were found that cited factors that could explain similarities or differences among institutional formularies.

B. Key Informant Panel (Factor Grouping & Validation)

To facilitate data collection by organizing the 56 factors into natural groupings, and also to validate that the factor list was complete, a key informant panel of 4 Pharmacy & Therapeutics Committee practitioners was assembled for a half-day meeting. The credentials of the panelists included:

- individuals who had participated on or supported provincial and RHA P&T Committees for up to 16 years.
- clinicians (physicians, pharmacists) up to ten years of patient care experience who also had training in drug evaluations, drug use, and economics,
- individuals with experience in large urban and small rural hospitals formulary processes as well as with government drug programs.

Procedures

The list of factors (without listing the citations) from Table #1 was circulated to the panelists in advance of the meeting for their review. At the meeting, the panelists were asked to identify any redundant factors and, based on their experiences, to identify any additional factors that influence formulary decision making.

Refining the list of factors:

- "Documentation" and "Literature review" were combined into a single new factor "Documentation/literature review"
- "Personal experience with manufacturer/representative" and "Past experience with manufacturer" were combined into a single new factor "Experience with manufacturer."
- "Alternate available (generic)" was changed to "Alternate available (generic, different molecule)"
- "Federal Drug Administration approval" was changed to "Federal Drug Administration/Therapeutic Products Program Notice of Compliance"

- "Ease of use" was changed to "Ease of use (patient)"

The panel also suggested that the following factors be added to the list:

- "Existence of a special program" – this factor would hold true when the health authority obtains special funding from government for an illness that affects a small portion of the population but is characterized as having disproportionately high treatment costs (i.e. patients with cystic fibrosis).
- "Community use of the drug" – this factor would take into consideration the likelihood that the drug will be used in treating the patient once they are discharged from hospital. Typically, patients are required to change medications for a condition depending on whether they are being treated in a hospital setting or managing their condition at home (i.e. patient will have different drugs in hospital than at home for managing high blood pressure).
- "Using formulary for educating care providers" – this factor arises when the RHA allows intern physicians to experiment with different drugs within the same class (i.e. drugs for managing hypertension) to learn which work best in varying patient situations.
- "Bonus (i.e. hiring pharmacists for P & T if buying drug) – this factor would occur when a drug company would offer to pay the salary of an additional pharmacist for a specified period of time to monitor the impact of their drug once it is introduced into the formulary. Typically, the pharmacist could also be asked to take on other duties of value to the RHA.
- "Increase in budget available for drugs" – this factor would take into consideration whether the RHA has increased the drug budget enough to allow for a new drug to be listed.
- "Antimicrobial resistance" – this factor relates to the drug's properties in treating patients with hospital-acquired infections that are resistant to existing medications.
- "Referral patterns of patient mix" – this factor refers to the patients being transferred to the RHA from rural areas. Specifically, will the new drug be used to treat most patients or only those coming from a specified location.
- "Impact on other departments (financial, technical)" – this factor refers to the impact the new drug would have on the budgets and workload of other hospital departments.
- "Community versus institutional cost" – this factor refers to the fact that some drugs are available for free or at extremely discounted prices to hospitals, but are expensive to patients managing a medical condition at home. While the drug may be appealing to hospital formularies, it can be unrealistic to assume that patients can afford it once they are at home.

This activity resulted in a total of 63 factors that may influence the formulary decision making process within institutions.

The panel was then asked to arrange the factors in natural groupings. This was accomplished using a management technique known as the "Affinity Diagram" (Brassard, 1989). In this activity, each factor was written on an individual post-it note, and the 63 Post-It™ notes were randomly posted on a large wall. The panelists, without discussion, arranged into columns the factors that they believed to be related. After some

final re-arranging of which column each Post-It™ note belonged to, the following groupings and group headings were identified.

1. Personal interests
Personal financial motivation

2. Pharmacologic Issues
Indications for use
Toxicity
Effectiveness
Antimicrobial resistance
Safety (published)
Adverse effects
Drug interactions
Clinical efficacy (published, unpublished)
Degree of risk

3. Issues Related to the Use of the Drug in Hospital vs in the Community
Community versus institutional cost
Community use of the drug
Referral patterns of patient mix

4. Quality of Evidence Supporting the Drug Submission
Observed adverse effects/negative experience with drug
Observed/perceived benefit of drug
Personal opinion
Care giver opinion
Physician consensus (other consensus)
Objectivity/credibility
Sources of information
Documentation/literature review
Patient outcomes (health status, health-related quality of life)

5. Patient Considerations
Patient acceptance
Ease of use (patient)
Flavour

6. Economic Issues
Drug budget (i.e. impact on total drug budget)
Estimated usage of drug
Cost (acquisition, daily)
Increase in budget available for drugs
Past prescribing volume of physicians
Case mix that drug can be used for
Bonus (i.e. hiring pharmacists for P & T if buying drug)

7. Drug Handling Issues
Drug administration
Product stability
Product storage issues
Preparation requirements
Drug strengths
Dosage frequency/forms
Pharmacokinetics

8. Issues Related to the Organization
Organization goals/context
Management structure
Hospital size
Internal ability to evaluate studies
Impact on other departments (financial, technical)
Data generated at local/organizational level
Sponsor (i.e. internal champion)
Interaction amongst members of P & T Committee
Inclusion of formulary body in data generation and analysis
Pharmacist consent to new drug being used
Existence of a special program
Physician convenience

9. Availability of Alternatives
Comparative data
Therapeutic advantage
Alternative available (generic, different molecule)

10. Post-decision Issues
Drug Utilization Reviews
Chart review by pharmacist on how drug is being used
Accountability for claims

11. Other External Considerations
Using formulary for educating care providers
Customer service of supplier
Experience with manufacturer
Ethical review
Years drug in use (product lifespan, obsolescence)
Federal Drug Administration/Therapeutic Products Program Notice of Compliance

Data Collection Advice

The panel was also asked for their advice on the best and most practical way to collect data that would allow analysis of factors that influence the formulary decision making process within Alberta RHAs. The panel suggested:

- writing the eight largest RHA P&T Committee Chairs and Pharmacy Directors asking to have each of their P&T Committee members participate in the data collection. The panel members felt that the eight largest RHAs had active P&T Committee structures, and that the smaller RHAs tended to mirror the decisions of one the larger RHAs.
- asking each P & T Committee member to complete no more than 5 – 8 surveys
- categorizing each P & T Committee member into one of Administration, Physician, and Pharmacist

C. Questionnaires

Two questionnaires were designed and administered: 1) Formulary Listing Status Questionnaire (see Appendix #1), and 2) Factors Influencing P&T Committees Questionnaire (see Appendix #2). Both questionnaires, along with their respective cover letters and the thesis proposal, were reviewed and approved by the University of Alberta Health Research Ethics Board (B: Health Research).

Formulary Listing Status Questionnaire

This questionnaire collected the data necessary for an analysis of the degree of similarity of RHA decision making on new pharmaceuticals.

To quantify the level of agreement between RHA formularies, a sample of pharmaceutical products that were approved for sale in Canada in 1996, 1997, or 1998 was identified. This resulted in a list of 86 drugs.

Questionnaires were distributed only to the RHAs that had expressed willingness to participate in the study. A cover letter and questionnaire were sent to the Pharmacy Director or Managers of 15 of the 17 RHAs since two RHAs declined participation in the study. In addition, a reminder letter was sent to non-respondents approximately one month later reminding them about the study and asking them to return their completed questionnaire.

The questionnaire allowed the respondents to select one of the following options for the listing status of each of the 86 drugs:

- Listed
- Not Listed
- Listed with Restriction
- Not Yet Reviewed
- Not Relevant to my RHA

Analysis of the questionnaire occurred using the following two ratios:

1. Raw Agreement, defined as:

$$\frac{\text{Number of Agreements}}{\text{Number of Agreements} + \text{Number of Disagreements}}$$

where:

Number of Agreements = the number of drugs with the same formulary status in two RHAs

Number of Disagreements = the number of drugs with different formulary status in two RHAs

2. Kappa, chance-adjusted concordance (Landis and Koch, 1977) , defined as:

$$K = \frac{Po - Pe}{1 - Pe}$$

where:

$$Po\,(proportion\ of\ observed\ agreement) = \left\{\frac{\text{number of agreements}}{\text{number of paired observations}}\right\}$$

$$Pe\,(proportion\ of\ chance\ agreement) = \left\{\frac{(\text{row marginal})(\text{column marginal})}{(\text{number of paired observations})2}\right\}$$

Kappa coefficients range from –1 to +1. A negative value indicates that the agreements occur less frequently than would be expected by chance alone. A positive value indicates that the agreements occur more frequently than would be expected by chance alone. A value of 0 indicates that agreements occur no more or less frequently than would be expected by chance alone.

The following benchmarks can be utilized to interpret Kappa coefficients (Landis and Koch, 1977):

Kappa coefficient	Strength of Agreement
< 0.00	Poor
0.00 – 0.20	Slight
0.21 – 0.40	Fair
0.41 – 0.60	Moderate
0.61 – 0.80	Substantial
0.81 – 1.00	Almost Perfect

Factors Influencing P&T Committees Questionnaire

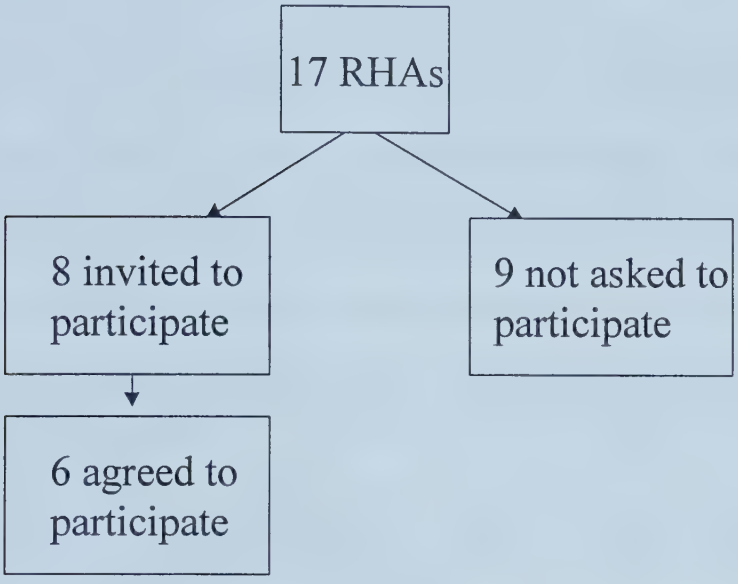
This questionnaire collected the data necessary for an analysis of the factors, and their relative importance, that influenced formulary decisions in the RHAs.

Data were collected on the level of impact each of the factors identified in the literature review and validated by the Key Informant Panel had on decision making in the RHAs. This information was extracted using a seven-point Likert scale. In addition, each respondent was asked to assess the impact each factor had on themselves (as Individuals) and on the entire P&T Committee (as a Group).

Questionnaires were distributed only to those RHAs who had expressed willingness to participate in the study. The Pharmacy Director and the P&T Committee Chairs in each of the eight largest RHAs were contacted by letter and a follow-up telephone call asking if the P&T Committee could be contacted to voluntarily complete the questionnaire. The eight largest RHAs were determined by the 1998/1999 annual budgets (Alberta Health, 1999). These RHAs, ranked in decreasing size of annual budget, were:

- Capital
- Calgary
- David Thompson
- Chinook
- East Central
- Lakeland
- Palliser
- Mistahia

A reminder letter was sent to non-respondents approximately one month later reminding them about the study and asking them to return their completed questionnaire.



Prior to conducting the survey, it was hypothesized that the Individual and Group responses on the influence each factor had on decision making would be similar. This was due to the expectation that the P&T Committee decision making process is based upon some level of consensus in arriving at decisions and therefore if there was significant disagreement on a particular issue, listing of that drug would not occur.

Analysis of the questionnaire was conducted using:

1. Descriptive statistics. Since the data were ordinal in nature, the statistics utilized were the median and the interquartile range (IQR).

2. Hypothesis testing. Since the data were ordinal, and that a one way comparison of pairs was to be undertaken, the Kruskal-Wallis One-Way Analysis of Variance by Ranks was utilized as the test statistic (Daniel, 1995).

   The hypothesis tested for each of the 11 factors was:

   Ho : The Individual and Group responses are the same

   Ha : The Individual and Group responses are not the same

III - Results

A. Literature Review

The following conclusions were drawn from the literature review:

- numerous factors influence the formulary decision making processes in institutions
- some factors are cited more frequently than others as influencing the decision making process
- no published articles were found that reported on the degree of similarity or difference among institutional formularies and thus no factors were identified that can explain the level of similarity or difference among institutional formularies.

Based on the results of the literature review, it can be concluded that:

- there is a continuum of influence that each factor has in the formulary decision making process. At one end of the continuum is no influence and at the other is highly influential.
- there are circumstances that change the relative influence of an individual factor on a case by case basis. Such circumstances could include timing, politics, review process, P & T Committee membership, etc.
- because there are many factors that influence formulary decisions and because the factors can vary in influencing the formulary decision, it is expected that there can be considerable differences between formularies of institutions.

B. Key Informant Panel

After consulting the key informant panel, it was concluded that little is known about the impact that specific factors have on pharmaceutical listing decisions. Much has been published about which factors ought to be considered during the formulary decision making process, but no analyses have been published that reveal the extent to which a particular factor affects listing decisions.

It was determined that it would be worthwhile to proceed with a data collection phase to ascertain what variation exists among formularies in Alberta RHAs, and what factors contribute to this variation.

C. Questionnaires

Formulary Listing Status Questionnaire

12 questionnaires were returned, with 9 of the 15 RHAs responding. Two of the RHAs returned more than one questionnaire, one returned three, and the other returned two. The two RHAs returning more than one questionnaire were RHAs responsible for large, rural areas with more than one major hospital, in which each of the hospitals maintain

their own formulary. Based on this rationale, it was decided to include the multiple questionnaires from two RHAs in the analyses.

The RHAs did not respond to the questionnaire in a uniform way. Some RHAs did not utilize the options available when responding (i.e. some did not select the choice "Listed with Restriction"), while others selected more than one option for a particular drug (i.e. "Not Listed" and "Not Relevant to my RHA"). The statistics utilized in the analysis required that all RHAs had to utilize the same group of response choices. As a result, it was necessary to re-code the responses into two categories: "Listed" and "Not Listed." All responses other than "Listed" were re-coded to be "Not Listed."

Appendix #3 contains the listing status of each of the 86 drugs within the RHAs. Table II displays the ratios representing raw agreement between each pair of the RHAs on the listing status of the 86 drugs.

Based on the raw agreement scores identified in Table II it would appear that the RHAs arrive at similar decisions 85% of the time. For RHAs H and I, it would appear that they have more than 90% agreement between their independent formularies.

Table II

Inter-Regional Health Authority (RHA) Raw Agreement in the Formulary Listing Status of New Drugs Launched in 1996, 1997, and 1998

RHA	RHA A	RHA B	RHA C	RHA D	RHA E	RHA F	RHA G	RHA H1	RHA H2	RHA H3	RHA I1	RHA I2
RHA A	----	0.80	0.78	0.85	0.84	0.81	0.67	0.83	0.81	0.85	0.70	0.84
RHA B	----	----	0.84	0.88	0.87	0.83	0.71	0.84	0.80	0.84	0.78	0.83
RHA C	----	----	----	0.86	0.87	0.87	0.78	0.88	0.85	0.88	0.87	0.85
RHA D	----	----	----	----	0.92	0.90	0.73	0.93	0.92	0.95	0.80	0.92
RHA E	----	----	----	----	----	0.91	0.77	0.92	0.93	0.94	0.81	0.91
RHA F	----	----	----	----	----	----	0.79	0.90	0.91	0.92	0.79	0.91
RHA G	----	----	----	----	----	----	----	0.78	0.77	0.76	0.79	0.77
RHA H1	----	----	----	----	----	----	----	----	0.94	0.95	0.83	0.90
RHA H2	----	----	----	----	----	----	----	----	----	0.97	0.81	0.88
RHA H3	----	----	----	----	----	----	----	----	----	----	0.90	0.92
RHA I1	----	----	----	----	----	----	----	----	----	----	----	0.84
RHA I2	----	----	----	----	----	----	----	----	----	----	----	----
	Overall Agreement =		0.85									

Although the level of agreement was high, some of the agreement is to be expected to occur purely by chance (Kramer and Feinstein, 1981). To correct for this phenomenon, chance-corrected agreement (Kappa) was tabulated. Table III presents the Kappa coefficients representing chance-corrected agreement between each pair of the RHAs on the listing status of the 86 drugs.

Based on chance corrected agreements, it would appear that the RHAs arrive at similar decisions only 15% of the time. This represents only "Slight" agreement between the RHAs on the formulary status of the 86 drugs.

For RHAs H and I, their chance-corrected agreement between their multiple formularies is only Slight to Fair.

Table III

Inter-Regional Health Authority (RHA) Agreement in the Formulary Listing Status of New Drugs Launched in 1996, 1997, and 1998
(kappa coefficients with 95% confidence intervals)
* denotes that level of agreement is not due to chance alone (p <= 0.05)

RHA	RHA A	RHA B	RHA C	RHA D	RHA E	RHA F	RHA G	RHA H1	RHA H2	RHA H3	RHA I1	RHA I2
RHA A	----	0.15 (-0.11 - 0.41)	0.05 (-0.18 - 0.28)	-0.04 (-0.09 - 0.01)	0.05 (-0.18 - 0.28)	0.01 (-0.20 - 0.23)	0.00 (-0.19 - 0.20)	-0.07 (-0.13 - -0.02)	-0.09 (-0.14 - -0.03)	-0.04 (-0.09 - 0.01)	-0.10 (-0.26 - 0.06)	0.05 (-0.18 - 0.28)
RHA B	----	----	0.32 (0.05 - 0.60)*	0.26 (-0.03 - 0.55)*	0.30 (0.00 - 0.59)*	0.12 (-0.14 - 0.38)	0.13 (-0.09 - 0.34)	0.06 (-0.16 - 0.28)	-0.09 (-0.15 - -0.03)	-0.04 (-0.09 - 0.01)	0.22 (-0.03 - 0.47)*	0.04 (-0.18 - 0.26)
RHA C	----	----	----	0.11 (-0.13 - 0.34)	0.30 (0.00 - 0.59)*	0.36 (0.06 - 0.65)*	0.34 (0.11 - 0.56)*	0.33 (0.03 - 0.63)*	0.17 (-0.11 - 0.44)	0.26 (-0.03 - 0.55)*	0.55 (0.31 - 0.78)*	0.17 (-0.11 - 0.44)
RHA D	----	----	----	----	-0.03 (-0.07 - 0.00)	-0.04 (-0.08 - 0.00)	0.04 (-0.08 - 0.16)	-0.03 (-0.06 - 0.00)	-0.03 (-0.07 - 0.00)	-0.02 (-0.05 - 0.00)	0.07 (-0.10 - 0.24)	-0.03 (-0.07 - 0.00)
RHA E	----	----	----	----	----	0.29 (-0.07 - 0.64)*	0.21 (0.01 - 0.41)*	0.18 (-0.19 - 0.55)	0.36 (-0.04 - 0.76)*	0.26 (-0.18 - 0.70)*	0.20 (-0.04 - 0.44)*	0.15 (-0.19 - 0.50)
RHA F	----	----	----	----	----	----	0.31 (0.10 - 0.53)*	0.13 (-0.19 - 0.45)	0.29 (-0.07 - 0.64)*	0.19 (-0.17 - 0.55)*	0.15 (-0.09 - 0.39)	0.29 (-0.07 - 0.64)*
RHA G	----	----	----	----	----	----	----	0.24 (0.04 - 0.43)*	0.21 (0.01 - 0.41)*	0.12 (-0.03 - 0.28)*	0.42 (0.20 - 0.64)*	0.21 (0.01 - 0.41)*
RHA H1	----	----	----	----	----	----	----	----	0.41 (0.00 - 0.83)*	0.31 (-0.18 - 0.80)*	0.23 (-0.01 - 0.47)*	-0.05 (-0.09 - -0.02)
RHA H2	----	----	----	----	----	----	----	----	----	0.56 (0.12 - 1.00)*	0.20 (-0.04 - 0.44)*	-0.06 (-0.10 - -0.02)
RHA H3	----	----	----	----	----	----	----	----	----	----	0.18 (-0.04 - 0.39)*	-0.03 (-0.07 - 0.00)
RHA I1	----	----	----	----	----	----	----	----	----	----	----	0.30 (0.05 - 0.55)*
RHA I2	----	----	----	----	----	----	----	----	----	----	----	----
		Overall Kappa =	0.15									

Factors Influencing P&T Committees Questionnaire

Of the 78 questionnaires distributed, 51 questionnaires were returned, a 65% response rate. Two questionnaires were returned from the same respondent, but with different responses. It was thought that the respondent photocopied the questionnaire and asked a colleague to also respond and therefore, both questionnaires were included in the analysis.

Each of the six RHAs that were sent questionnaires had non-respondents. Non-respondents ranged from three to five in each RHA except for one. In that particular RHA, there were 10 non-respondents.

In some cases, respondents provided two scores for an individual factor. In these cases, the lower of the two scores was selected for the analysis.

With respect to the question on which category the respondent belonged to, in some cases, two responses were selected. In these cases, the profession was included in the analysis. For example, the respondent selected "Physician" and "Other" and wrote in Pathologist. In this case, "Physician" was the response included in the analysis.

The factors, in decreasing median score, that were reported to influence INDIVIDUAL and the GROUP P&T Committee members in their decision making are summarized in Tables IV and V.

The seven-point Likert scale utilized was:

Almost None	Hardly Any	A Little	Some	A Fair Bit	A Lot	A great deal
1	2	3	4	5	6	7

Table IV – Factors Reported as Influencing Individual Decision-Making

Factor	Median Score	Interquartile Range (IQR)
1) Pharmacologic Issues	7	1
2) Quality of Evidence Supporting The Drug Submission	6	1
3) Economic Issues	6	1.25
4) Availability of Alternatives	6	2
5) Issues Related to the Use of the Drug in Hospital vs in the Community	5	1
6) Post-decision Issues	5	2
7) Issues Related to the Organization	4.5	1
8) Patient Considerations	4	1
9) Drug Handling Issues	4	2
10) Other External Considerations	4	2
11) Personal Interests	1	0.25

Table V – Factors Reported as Influencing Group Decision-Making

Factor	Median Score	Interquartile Range (IQR)
1) Pharmacologic Issues	6	1
2) Quality of Evidence Supporting The Drug Submission	6	1
3) Economic Issues	6	2
4) Availability of Alternatives	6	2
5) Issues Related to the Organization	5	1
6) Issues Related to the Use of the Drug in Hospital vs in the Community	5	2
7) Post-decision Issues	5	2
8) Other External Considerations	5	2
9) Drug Handling Issues	5	2.25
10) Patient Considerations	4	1
11) Personal Interests	2	2.25

In comparing the Individual and Group rankings, the four factors reported to exert the greatest influence on the decision making were the same, and in the same order. These were: 1) pharmacologic issues; 2) Quality of Evidence Supporting the Drug Submission; 3) Economic Issues; and 4) Availability of Alternatives.

Similarly, the factor Personal Interests was reported to influence the Individual and the Group the least in decision making.

Figures I to XI present the frequency distributions of the responses.

Figure I – Respondents by Professional Category

N = 51

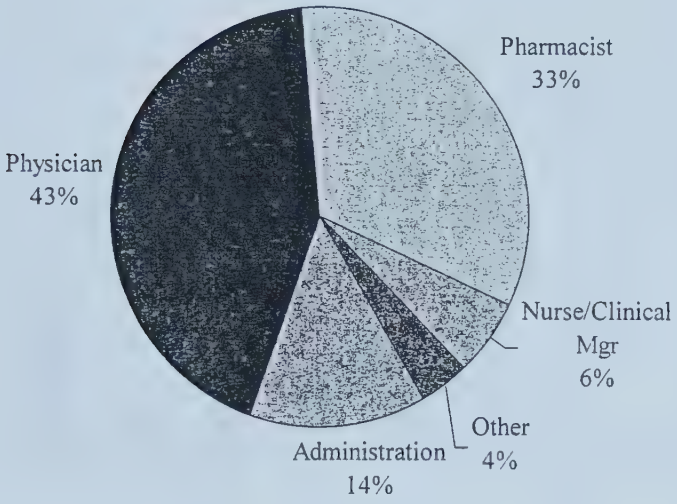


Figure II – Percentage of P&T Committee Meetings Attended by Respondents

N = 51

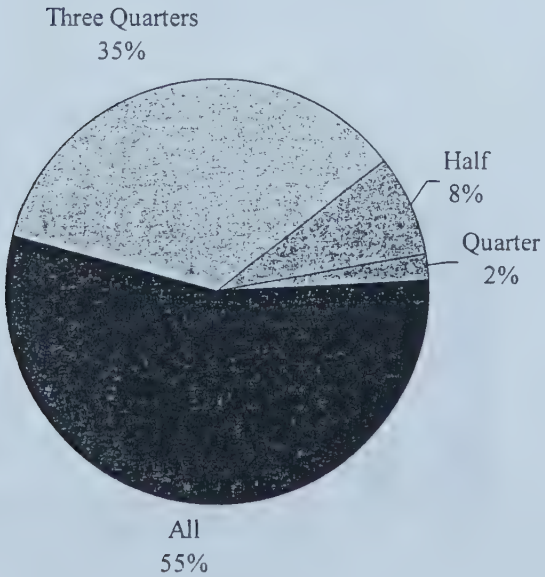


Figure III – Impact of Personal Interests

N = 51
Individual - Median = 1, IQR = 0.25
Group - Median = 2, IQR = 2.25

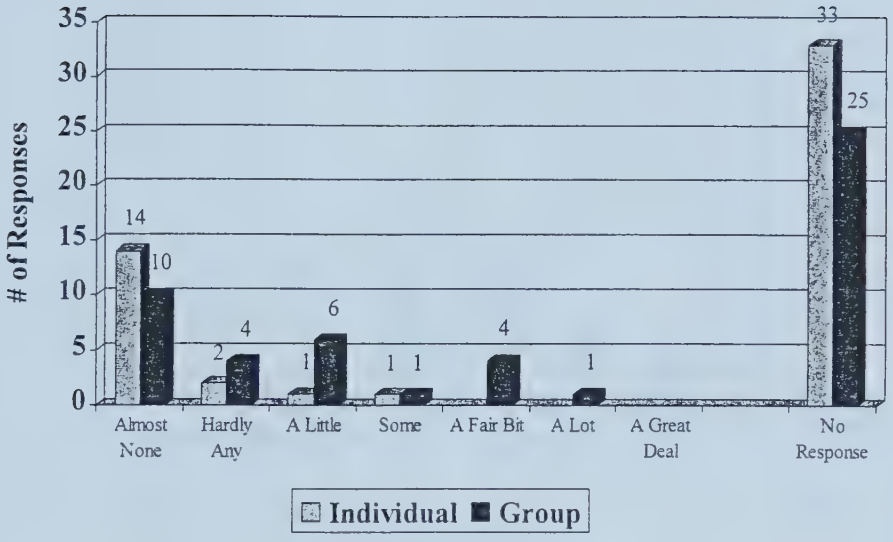


Figure IV – Impact of Pharmacologic Issues

N = 51
Individual - Median = 7, IQR = 1
Group - Median = 6, IQR = 1

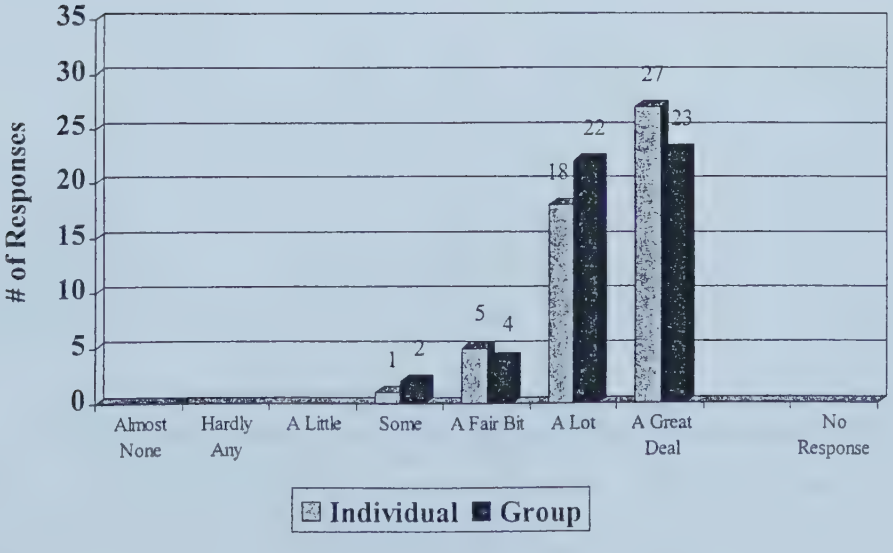


Figure V – Impact of Issues Related to the Use of the Drug in Hospital vs in the Community

N = 51
Individual - Median = 5, IQR = 1
Group - Median = 5, IQR = 2

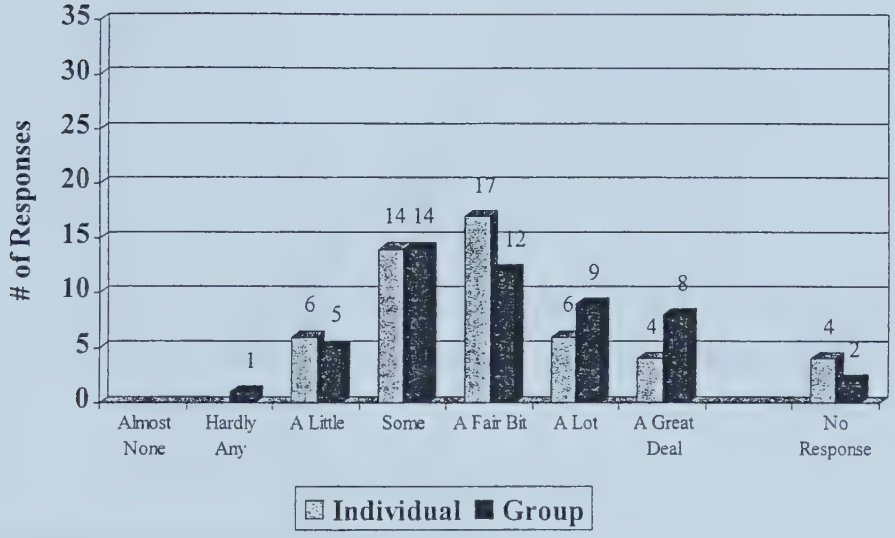


Figure VI – Impact of Quality of Evidence Supporting the Drug Submission

N = 51
Individual - Median = 6, IQR = 1
Group - Median = 6, IQR = 1

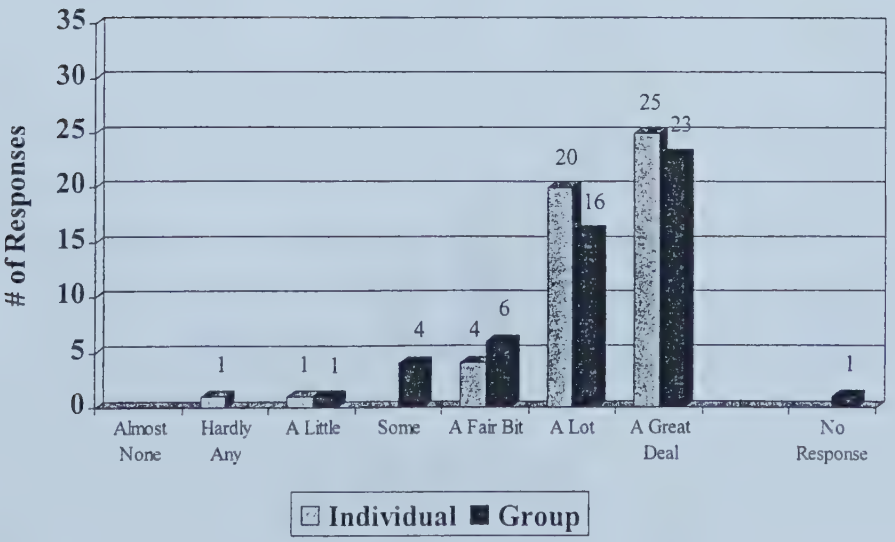


Figure VII – Impact of Patient Considerations

N = 51
Individual - Median = 4, IQR = 1
Group - Median = 4, IQR = 1

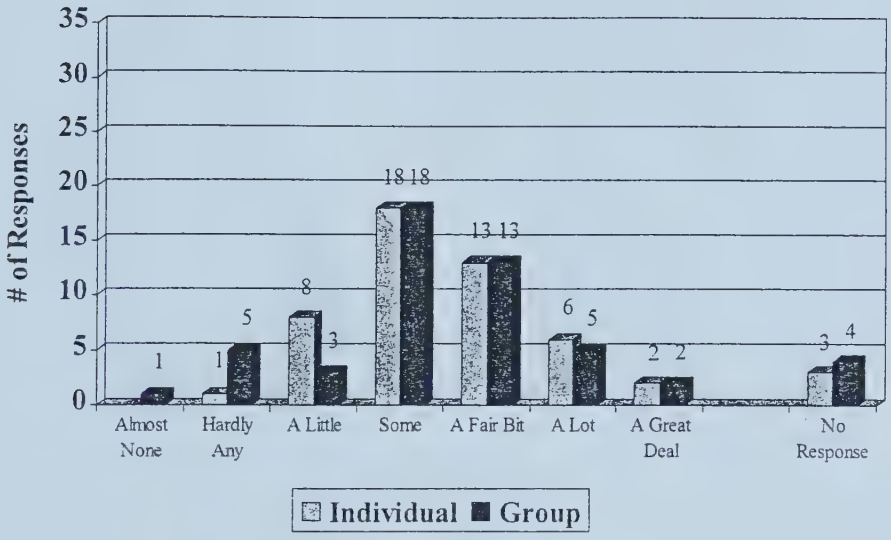


Figure VIII – Impact of Economic Issues

N = 51
Individual - Median = 6, IQR = 1.25
Group - Median = 6, IQR = 2

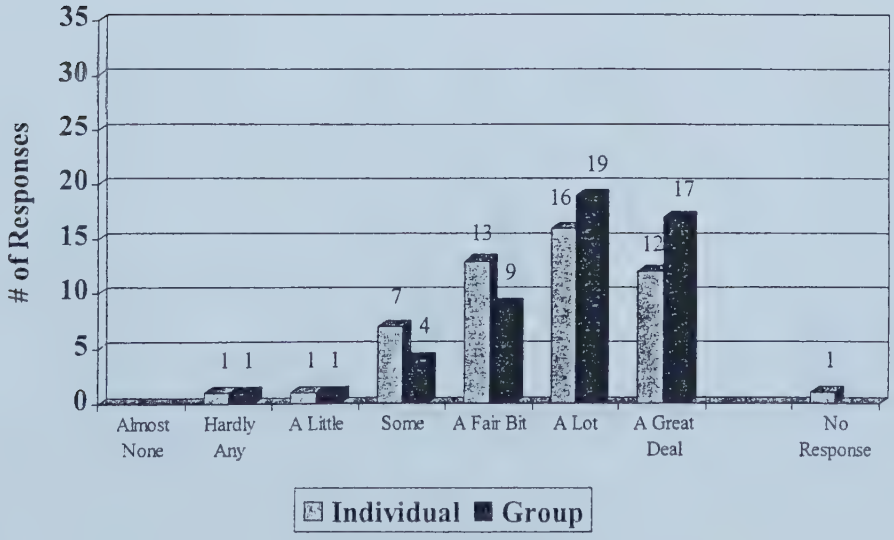


Figure IX – Impact of Drug Handling Issues

N = 51
Individual - Median = 4, IQR = 2
Group - Median = 5, IQR = 2.25

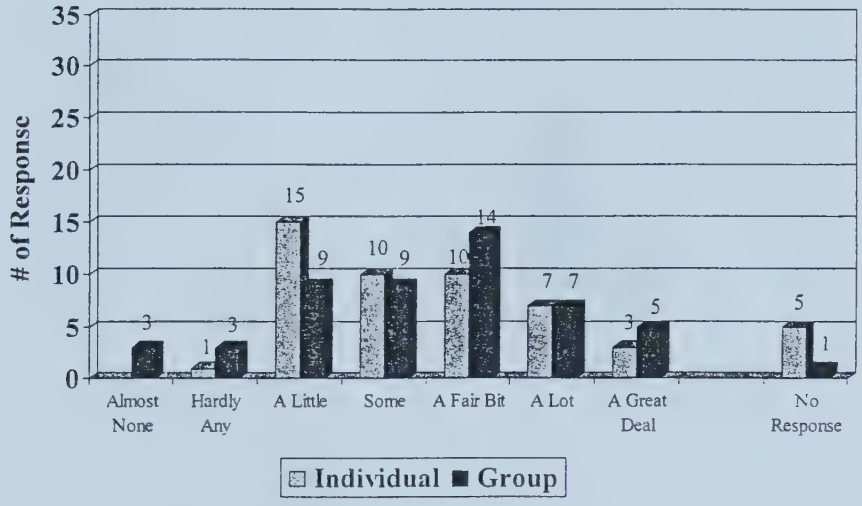


Figure X – Impact of Issues Related to the Organization

N = 51
Individual - Median = 4.5, IQR = 1
Group - Median = 5, IQR = 1

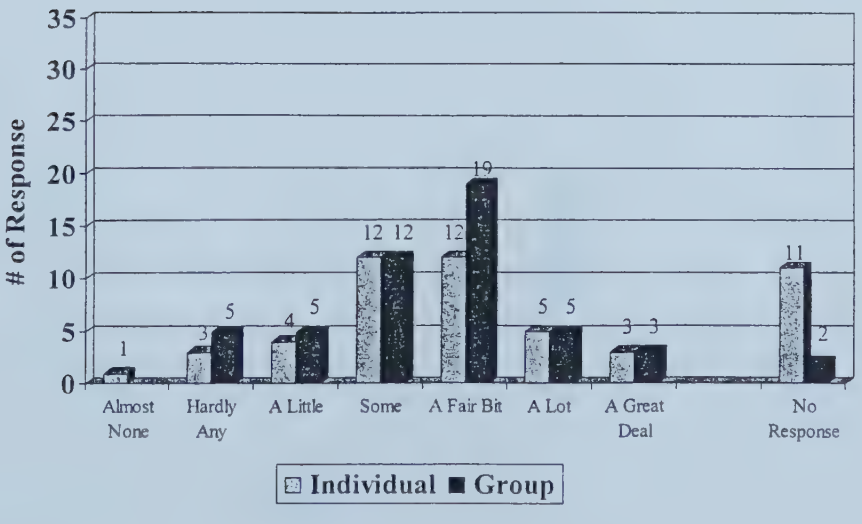


Figure XI – Impact of Availability of Alternatives

N = 51
Individual - Median = 6, IQR = 2
Group - Median = 6, IQR = 2

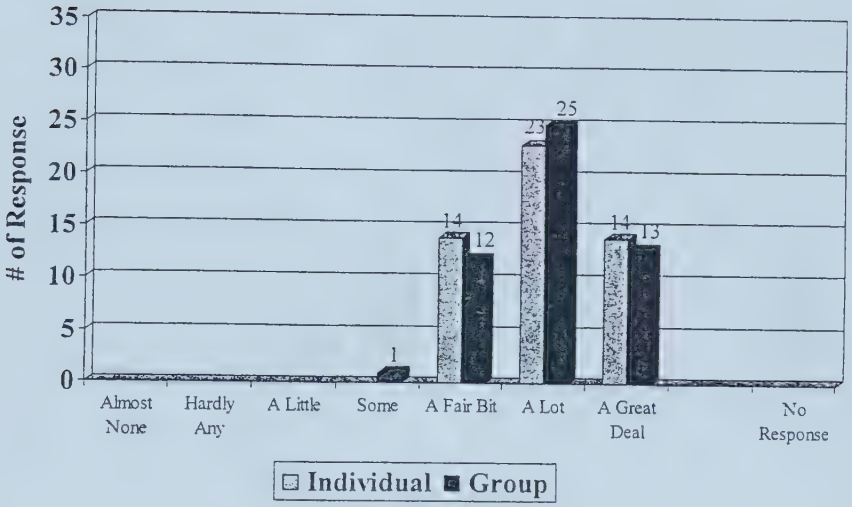


Figure XII – Impact of Post-Decision Issues

N = 51
Individual - Median = 5, IQR = 2
Group - Median = 5, IQR = 2

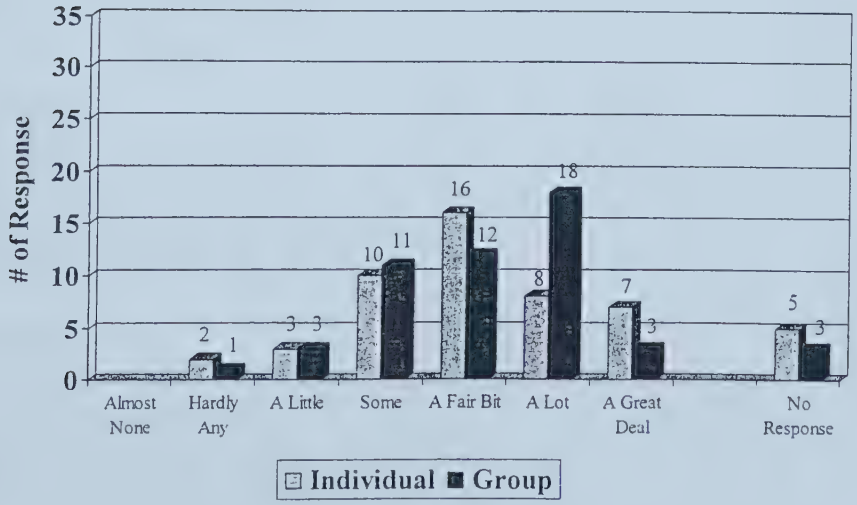
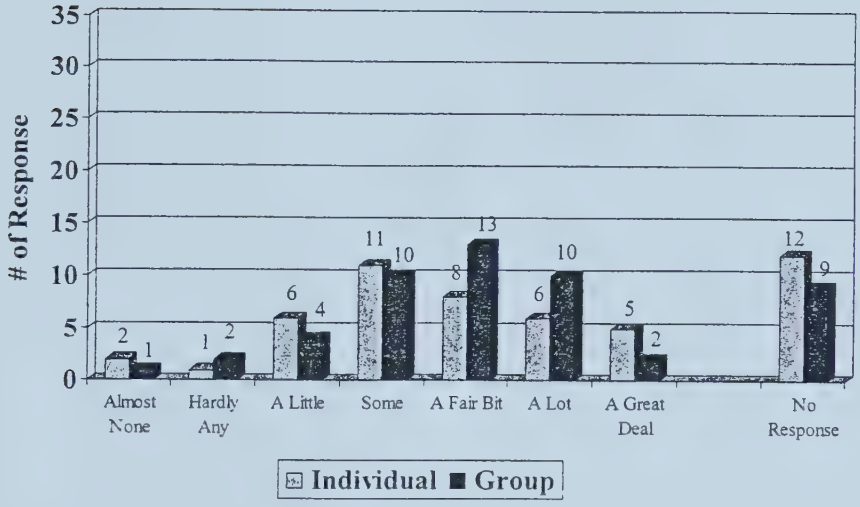


Figure XIII – Impact of Other External Considerations

N = 51
Individual - Median = 4, IQR = 2
Group - Median = 5, IQR = 2



Analyses were also conducted to stratify respondents by profession (see Table VI). The analysis was conducted using the Individual responses.

The factors reported to exert the most influence on each of the professional groups were:

For Physicians
- pharmacologic issues (median = 7)
- quality of evidence supporting submission (median = 6.5)
- availability of alternatives (median = 6)
- post-decision issues (median = 6)
- economic issues (median = 6)

For Pharmacists
- quality of evidence (median = 7)
- pharmacologic issues (median = 6)
- availability of alternatives (median = 6)
- economic issues (median = 6)

For Administration
- quality of evidence quality of evidence supporting submission (median = 7)
- economic issues (median = 7)
- pharmacologic issues (median = 6)
- availability of alternatives (median = 6)
- organizational issues (median = 6)

Even after stratifying by respondent professional category, the factors reported to exert the most influence on formulary decision-making remained:

- Pharmacologic Issues
- Quality of Evidence Supporting The Drug Submission
- Economic Issues
- Availability of Alternatives

Table VI

Factors That Influence Individual Decision-Making by Profession

Question	Physicians (N = 22)	Pharmacists (N = 17)	Administration (N = 7)	Nurse/Clinical Mgr (N = 3)	Other (N = 2)
Personal Interests	Median = 1 IQR = 0	Median = 1 IQR = 0	Median = 3 IQR = 0	Median = 2.5 IQR = 3	Median = 1 IQR = 0
Pharmacologic Issues	Median = 7 IQR = 1	Median = 6 IQR = 1	Median = 6 IQR = 1	Median = 6 IQR = 1	Median = 5.5 IQR = 1
Use of Drug in Community vs Hospital	Median = 4.5 IQR = 1.75	Median = 4 IQR = 1	Median = 5 IQR = 1.25	Median = 6 IQR = 1	Median = 5 IQR = 0
Quality of Evidence	Median = 6.5 IQR = 1	Median = 7 IQR = 1	Median = 7 IQR = 4	Median = 6 IQR = 0	Median = 6.5 IQR = 1
Patient Considerations	Median = 4 IQR = 2	Median = 4 IQR = 1	Median = 4 IQR = 1	Median = 5 IQR = 1	Median = 4 IQR = 4
Economic Issues	Median = 5 IQR = 2	Median = 6 IQR = 1.75	Median = 7 IQR = 2	Median = 6 IQR = 2	Median = 6 IQR = 0
Drug Handling Issues	Median = 4 IQR = 2	Median = 4 IQR = 2	Median = 5.5 IQR = 2.5	Median = 5 IQR = 4	Median = 6 IQR = 0
Organizational Issues	Median = 4 IQR = 2	Median = 4.5 IQR = 1	Median = 6 IQR = 3	Median = 5 IQR = 3	Median = 5 IQR = 0
Availability of Alternatives	Median = 6 IQR = 2	Median = 6 IQR = 1	Median = 6 IQR = 2	Median = 6 IQR = 1	Median = 5.5 IQR = 1
Post-decision Issues	Median = 5 IQR = 1	Median = 5 IQR = 2.5	Median = 5 IQR = 2	Median = 4 IQR = 3	Median = 6 IQR = 0
External Considerations	Median = 4 IQR = 2	Median = 4 IQR = 1	Median = 4 IQR = 3	Median = 6 IQR = 3	Median = 6 IQR = 0

In testing the hypotheses, it was found that ($p<=0.05$):

Factor	Decision	χ^2
Personal Interests	Reject Ho (i.e. Individual and Group responses NOT the same)	5.487
Pharmacologic Issues	Accept Ho (i.e. Individual and Group responses ARE the same)	19.313
Issues Related to the Use of the Drug in Hospital vs in the Community	Reject Ho (i.e. Individual and Group responses NOT the same)	7.329
Quality of Evidence Supporting The Drug Submission	Accept Ho (i.e. Individual and Group responses ARE the same)	11.564
Patient Considerations	Accept Ho (i.e. Individual and Group responses ARE the same)	14.912
Economic Issues	Reject Ho (i.e. Individual and Group responses NOT the same)	2.835
Drug Handling Issues	Reject Ho (i.e. Individual and Group responses NOT the same)	9.069
Issues Related to the Organization	Accept Ho (i.e. Individual and Group responses ARE the same)	13.025
Availability of Alternatives	Accept Ho (i.e. Individual and Group responses ARE the same)	13.059
Post-decision Issues	Reject Ho (i.e. Individual and Group responses NOT the same)	6.462
Other External Considerations	Reject Ho (i.e. Individual and Group responses NOT the same)	12.446

IV - Discussion

The objectives of the project were to:
A. examine the level of agreement between RHA formularies, and
B. identify the factors that influence Pharmacy & Therapeutics (P&T) Committee members in their decision making.

A. Level of Agreement in RHA Formulary Decisions

The study found that there is little variation in the formulary decisions taken by RHAs in the province of Alberta. On average, 85% of the decisions taken by the RHAs were in agreement, using raw agreement scores.

However, when the agreement scores were chance-corrected using the Kappa statistic, only "Slight" agreement was found between the RHA decisions. The mean Kappa coefficient was found to be 0.15, representing almost no agreement beyond that that could be expected by chance alone.

This discrepancy is partially explained by the construct of the Kappa statistic. The Kappa statistic requires that high chance-corrected agreement scores are comprised of evenly distributed positive and negative agreements between two RHAs. For example, maximizing the Kappa coefficient in a 2 x 2 contingency table requires having total agreement scores evenly distributed amongst the "Listed" and "Not Listed" cells. In the case of the RHA decisions on the sample of 86 drugs, this was not the case .

It was found that there was a predominance of agreement in "Not Listed" decisions, which contributed to lower Kappa coefficients. There was a tendency for RHAs not to approve drugs on the formulary. On average, between every pair of RHAs, 71 of the 86 responses contained a "Not Listed" response from both RHAs. This represents a predominance of RHAs decisions not to list new drugs.

Perhaps an even more important finding was that RHAs of similar size did not reach similar decisions very often where either decided to list a new drug. For example, RHA A and RHA B are of similar size, annual operating budget, and patient composition. When the listing status where either RHA decided to list a new drug is examined, it was shown that they rarely arrive at similar decisions. This was based on examining all drugs that were listed by either RHA. This occurred 20 times. In only three of these instances were the drug listed by both RHAs.

These findings are important in that there was no previous published assessments comparing the agreement between decisions taken by hospitals or RHAs on drugs.

Given the relatively recent evolution of evidence-based decision making, the efforts of the Alberta RHAs to harmonize their formulary review processes, and the independent nature of health care decision making at the patient level, the raw agreement scores were higher than expected.

The overall Kappa coefficient (0.15) was lower than expected. Kappa coefficients reported in the Anis et al. study (kappa-like statistic = 0.20) and Gregoire et al. (kappa statistic = 0.32) were higher. At the outset, it was expected that the Kappa coefficients for this study would be higher than in the two other studies as the RHAs have relatively similar patient populations. The RHAs also all fall under the jurisdiction of the same government. This should have contributed to higher Kappa coefficients than found in the Anis et al. and Gregoire et al. studies, as they compared decisions taken on new drugs by different provincial government, each with its own political agenda which in turn influences their decisions.

Another limitation was the respondent utilization of a few response options within the questionnaire. Since the respondents did not uniformly use all selections regarding the status of the drug on their formulary, it was necessary to aggregate the data. Most of the aggregation was to the "Not Listed" choice. This also contributed to lower Kappa coefficients.

A third limitation may have been the temporal nature of decision making within the RHAs. Smaller organizations tend to take a longer period to make decisions on drugs (D'Sa, Hill, and Stratton, 1994). As a result, the smaller RHAs may not have actively considered many of the 86 drugs listed in the questionnaire by the time of completing the questionnaire. However, the data did not support this. In fact, some of the smaller RHAs tended to list more drugs on their formularies than did the larger ones, regardless of the year in which the drugs were approved for sale.

A fourth limitation is the rigor with which RHAs enforce the formularies. In some RHAs, physicians are not allowed to prescribe drugs that are not contained in the formulary. In other RHAs, physicians may prescribe drugs not included on the formulary. Depending on each RHA, this policy can have a distorting effect on the formulary listing decision.

The implications of these results can contribute importantly to RHA decision making. From a health policy perspective, the justification for multiple formulary decision-making processes in Alberta can be questioned. This is because, on average, the formulary decisions taken are in high concordance among RHAs. Since considerable resources are expended within each RHA on formulary review and decision-making, and because most decisions are similar, it would seem that an opportunity exists to consolidate formulary review and decision-making processes. On the other hand, "buy in" or compliance with decisions might be lower if the decisions are not made locally. Similarly, important innovations can be discovered when two or more organizations approach the same issue from different perspectives, thus arriving at different decisions even though they use the same evidence. Perhaps a forum enabling RHAs to share the information they use in their formulary decision making processes could be an important first step.

Another implication is the long term effect of not listing new drugs on the formulary. Are the new drugs not listed because of cost issues? Are they not listed due to complicated handling issues? What is the impact on patient health outcomes of frequently deciding not to list new drugs?

Finally, in designing effective P&T processes, RHAs should give consideration to the value added by a formulary. If physicians can prescribe drugs not included on the formulary, the wisdom of expending significant resources maintaining a formulary can be questioned.

B. Factors Influencing P&T Committee Decisions

The study confirmed that many factors are reported as influencing formulary decisions. The factors reported as most strongly influencing P&T Committee decision making, whether at the individual or group level, were:

- Pharmacologic Issues
- Quality of Evidence Supporting The Drug Submission
- Economic Issues
- Availability of Alternatives

The factor reporting as exerting the least influence on P&T Committee decision making, both at the individual and group level, was:

- Personal Interests

The study also found that considerable differences existed between the reported impact some factors had on individual members as compared to the Committee as a whole in influencing P&T Committee decisions. This is an important study outcome, as little was available in the literature to compare the influence that factors had on the individual and the Committee as a whole.

Based on the literature review and the Key Informant Panel, it was expected that there would be numerous factors that influence P&T Committee decisions. However, what was unexpected were the relatively minor differences in influence that each factor was reported to have on decision making. There was little to discriminate between the factors reported as influencing the decision making process.

A limitation of the study was that a large number of respondents that did not answer the question regarding the impact that Personal Interests had on P&T Committee decision making. Similarly, there was a high degree of non-response to the question regarding the impact that Other External Considerations had on P&T Committee decision making. These politically correct responses might have been expected.

Another limitation was that the study did not pinpoint the specific factors that contributed to variations in decisions on a drug by drug basis. The study design did not ask respondents to identify which factor was important in the decision making for each drug. Instead, respondents replied generally as to the influence each factor had on the P&T Committee decision making process. In large part, this design was based on the advice from the Key Informant Panel that it would be extremely difficult to obtain accurate retrospective factor importance ratings from P&T Committee members. In fact, it was

stated that it would be unlikely that P&T Committee members would respond to any questionnaire requiring more than a few minutes to complete.

The implications of these results are important for RHAs and other hospital P&T Committees. There is considerable difference between the importance some factors have on individual and the Committee. This raises an important question for designing effective processes for managing the decision making process in P&T Committees. Is consensus the best method of decision making on such Committees? Is a silent ballot vote a more effective mechanism? Regardless of the method, significant attention should be paid to ensuring individual committee member perspectives are reconciled with group decisions within P&T Committees.

Another implication is the process used to objectify the amalgamation of each of the factors when a decision is being made. If it is true that most of the factors hold a very high level of influence on P&T Committee decision making, how are these factors reconciled into a decision? For example, how are Economic Issues balanced with Pharmacologic Issues? When does Quality of Evidence supercede Economic Issues? This is a difficult organization/group design issue that can lead to inappropriate decisions if it is not properly managed.

C. Conclusion

P&T decision making is an important example of evidence-based decision making in health care. This study has found that there are at least eleven groups of factors that were reported to influence P&T Committee decision making. It also found that the factors have different influence on the individual and the overall Committee. Furthermore, it was shown that RHAs tend to reject the addition of new drugs to RHA formularies.

Given that there is a high degree of raw agreement on the formulary status of the RHAs, a question can be raised regarding the need for independent formulary review bodies within each RHA. Because decisions taken are similar in most cases, could not the RHAs implement methods for sharing the information utilized in formulary decision making if not going as far as a unified formulary review body, with independent formulary decision making? This would relieve a large burden on the relatively few formulary review specialists in Alberta and nationally.

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Appendix #1

6 December 2000

Intended Recipient

Dear _____:

I very much appreciate the decision by your Pharmacy & Therapeutics (P&T) Committee to allow participation in the following research project being undertaken by the Institute of Health Economics. The project is also the thesis component of my Master in Public Health degree at the University of Alberta.

Project: Variation in Institutional Pharmaceutical Formularies

Investigators: Joseph Gebran, MPH Student, University of Alberta
Ph: 780-413-1521
Devidas Menon, Institute of Health Economics & University of Alberta
Ph: 780-448-4881

Purpose:

- Examine and document the decisions of Alberta's Regional Health Authorities (RHAs) on a few recently introduced drugs. For this component, the attached questionnaire will collect the data required.
- identify the general factors (and their relative importance) that contribute to decisions about listing new drugs. For this component, a separate questionnaire will be sent to each member of your core P&T Committee in order to collect the data required.

The results of the project will be shared with all RHA P&T Committees that participate in the study. Names or any other identifying information of individuals completing the questionnaire will be kept confidential and will not be used in any presentations or publications of the findings. The study data will be kept in a secure area accessible only to the researchers for at least five years following the study completion as mandated by the University of Alberta Research Policies and Services Manual, sections 5.2 and 7.5.

Your participation in the project is voluntary and you have the right to refuse to answer any specific question. If you do choose to participate, I would appreciate it if you could complete the questionnaire by 15 January 2001 and return it by mail using the attached, pre-addressed, pre-stamped envelope. Completing the questionnaire should take approximately 30 minutes.

Please contact me should you have any questions about the questionnaire or the study. My email address is jgebran@exceedia.com. Should you have concerns regarding the study, you may contact Dr. Devidas Menon or the Department of Public Health Sciences at the University of Alberta 780-492-6408.

Sincerely,

Joseph Gebran

/kls

Formulary Listing Status of
Approved New Active Substances (1996, 1997, 1998)
Joseph Gebran, University of Alberta, Institute of Health Economics

Instructions: Listed below are drugs that were approved for sale by the Health Protection Branch in 1996, 1997, and 1998. Included in the lists are New Active Substances, excluding contrast medium, cancer drugs, and blood bank products. Please indicate (using an **X**) the formulary listing status of each of the following products. Please provide only one response per product.

1996

Brand Name	Active Ingredient	Formulary Status			Not Yet Reviewed	Not Relevant to my RHA
		Listed	*Not Listed*	*Listed with Restriction*		
Acel-P	Acellular pertussis vaccine adsorbed					
Ambien	Zolpidem tartrate					
Clivarine	Reviparin sodium					
Dexferrum	Iron dextran					
Dynabac	Dirithromycin					
Ethyol	Amifostine					
Humalog	Insulin lispro injection					
Infanrix	Diptheria, tetanus and acellular pertussis vaccine					
Invirase	Saquinavir mesylate					
Megalone	Fleroxacin					
Merrem	Meropenem					
Moru-Viraten Berna Vaccine	Measles virus vaccine (live Attenuated) / Water / Rubella virus vaccine					
Naropin Injection	Ropivacaine hydrochloride					
Nimbex Injection	Cisatracurium besylate					

1996 cont.

Brand Name	Active Ingredient	Formulary Status			Not Yet Reviewed	Not Relevant to my RHA
		Listed	*Not Listed*	*Listed with Restriction*		
Norprolac	Quinagolide hydrochloride					
Norvir	Ritonavir					
Panto-Byk	Pantoprazole sodium sesquihydrate					
Redux	Dexenfluramine					
Reopro	Abciximab					
Revex	Nalmefene hydrochloride					
Suprane	Desflurane					
Trusopt	Dorzolamide hydrochloride					
Ultiva Injection	Remifentanil hydrochloride					
Valtrex	Valacyclovir hydrochloride					
Vexol	Rimexolone					
Zerit	Stavudine					
Zyprexa tabs	Olanzapine					

Brand Name	Active Ingredient	Formulary Status			Not Yet Reviewed	Not Relevant to my RHA
		Listed	Not Listed	Listed with Restriction		
Accolate	Zafirlukast					
Agrylin Capsules	Anagrelide as hydrochloride					
Allegra	Fexofenadine hydrochloride					
Alphagan Ophtalmic Sol.	Brimonidine tartrate					
Anzemet	Dolasetron mesylate					
Aricept	Donepezil hydrochloride					
Biltricide tabs	Praziquantel					
Bondronat	Ibandronate acid					
Cerebyx inject.	Fosphenytoin sodium					
Cerezyme	Imiglucerase					
Copaxone for Injection	Glatiramer acetate					
Cytogam	Cytomegalovirus immune globulin intravenous (Human)					
Diovan caps	Valsartan					
Dr. Scholl's Athlete's Foot Cream	Butenafine hydrochloride					
Duratocin	Carbetocin					
Flolan for Injection	Epoprostenol sodium					
Foradil Dry Powder Capsules for Inhalation	Formoterol fumarate					

1997 cont.

Brand Name	Active Ingredient	Formulary Status			Not Yet Reviewed	Not Relevant to my RHA
		Listed	*Not Listed*	*Listed with Restriction*		
Fraxiparine Injection	Nadroparin calcium					
Gonal-F	Follitropin alpha					
Leucomax	Molgramostim					
Levaquin Tablets and Injection	Levofloxacin					
Lipitor Tablets	Atorvastatin calcium					
Oxizole	Oxiconazole nitrate					
Patanol	Olapatadine hydrochloride					
Puregon	Follitropin beta					
Requip	Ropinirole hydrochloride					
Respigam	Respiratory syncytial virus immune globulin intravenous (Human)					
Rezulin	Troglitazone					
Seroquel Tablets	Quetiapine fumarate					
Skelid Tablet	Tiludronate disodium					
Tasmar	Tolcapone					
Tazorac Gel	Tazorotene					
Topamax Tablets	Topiramate					
Xalatan	Latanoprost					

1998

Brand Name	Active Ingredient	Formulary Status			Not Yet Reviewed	Not Relevant to my RHA
		Listed	Not Listed	Listed with Restriction		
Amerge	Naratriptan (hydrochloride)					
Atacand	Candesartan Cilexetil					
Avapro	Irbesartan					
Azopt ophthalmic suspension	Brinzolamide					
Baycol	Cerivastatin Sodium					
Detrol	Tolterodine L-Tartrate					
Emadine Ophthalmic Solution	Emedastine Difumarate					
Evista	Raloxifene Hydrochloride					
Flomax	Tamsulosin Hydrochloride					
Glyset	Miglitol					
Lymerix	Lipoprotein-OspA antigen recombinant					
Mirapex	Pramipexole dihydrochloride monohydrate					
Plavix	Clopidogrel bisulfate					
Raxar	Grepafloxacin Hydrochloride					
Rebif	Interferon beta-1a					
Regranex	Becaplermin gel					
Rescriptor	Delavirdine mesylate					
Singulair	Montelukast Sodium					
Trovan (IV)	Alatrofloxacin Meslyate					
Trovan (Tablets)	Trovafloxacin Meslyate					
Varivax	Varicella vaccine, live, attenuated (Oka/Merck Strain)					
Viracept	Nelfinavir meslyate					

1998 cont.

Brand Name	Active Ingredient	Formulary Status			Not Yet Reviewed	Not Relevant to my RHA
		Listed	Not Listed	Listed with Restriction		
Viramune	Nevirapine					
Wellbutrin SR	Bupropion Hydrochloride					
Zomig	Zolmitriptan					

RHA: _____ **Date:** _____

Name of Person Completing Form: _____ **(please print)**

Appendix #2

5 December 2000

Intended Recipient

Dear _____:

I very much appreciate the decision by your Pharmacy & Therapeutics (P&T) Committee to allow participation in the following research project being undertaken by the Institute of Health Economics. The project is also the thesis component of my Master in Public Health degree at the University of Alberta.

Project: Variation in Institutional Pharmaceutical Formularies

Investigators: Joseph Gebran, MPH Student, University of Alberta
Ph: 780-413-1521
Devidas Menon, Institute of Health Economics & University of Alberta
Ph: 780-448-4881

Purpose:

- Examine and compare the decisions of Alberta's Regional Health Authorities (RHAs) on a few recently introduced drugs. For this component, a separate questionnaire will be sent to your RHA Pharmacy Director.
- identify the general factors (and their relative importance) that contribute to decisions about listing new drugs. For this component, the attached questionnaire will collect the data required.

The results of the project will be shared with all RHA P&T Committees that participate in the study. Names or any other identifying information of individuals completing the questionnaire will be kept confidential and will not be used in any presentations or publications of the findings. The study data will be kept in a secure area accessible only to the researchers for at least five years following the study completion as mandated by the University of Alberta Research Policies and Services Manual, sections 5.2 and 7.5.

Your participation in the project is voluntary and you have the right to refuse to answer any specific question. If you do choose to participate, I would appreciate it if you could complete the questionnaire by 15 January 2001 and return it by mail using the attached, pre-addressed, pre-stamped envelope. Completing the questionnaire should take approximately 15 minutes.

Please contact me should you have any questions about the questionnaire or the study. My email address is jgebran@exceedia.com. Should you have concerns regarding the study, you may contact Dr. Devidas Menon or the Department of Public Health Sciences at the University of Alberta 780-492-6408.

Sincerely,

Joseph Gebran

/kls

Factors Influencing Pharmacy & Therapeutics Committee Decisions
Joseph Gebran, University of Alberta and Institute of Health Economics

Instructions

Please complete this questionnaire based on your experiences and opinions. There are no right or wrong answers. The entire survey should take no longer than 15 minutes to complete.

There are two sections to this questionnaire. The first section is to determine the factors that influenced YOUR decisions when drugs have been reviewed for formulary inclusion/exclusion at your P&T Committee. The second section is to determine your views on the factors that influenced THE GROUP (Committee) decisions.

Please put a check mark (✓) next to the factors which apply in each section. Then please circle the rating that best describes the amount of impact that factor had on the decision.

Factors that influence YOUR decisions

(✓) all that apply	Factor	Amount of Impact						
		Almost none	Hardly any	A little	Some	A fair bit	A lot	A great deal
☐	1. **Personal Interests** ie. personal financial motivation or other factors that benefit you directly	1	2	3	4	5	6	7
☐	2. **Pharmacologic Issues** ie. issues such as indications for use, toxicity, effectiveness, safety, adverse effects, drug interactions	1	2	3	4	5	6	7
☐	3. **Issues Related to the Use of the Drug in Hospital vs in the Community** ie. cost of drug in the community vs in hospital, drug usage patterns in community vs in hospital	1	2	3	4	5	6	7
☐	4. **Quality of Evidence Supporting the Drug Submission** ie. reliability/objectivity/credibility of the data available on the drug, care giver opinions regarding the drug, quality of documentation/literature review on the drug, patient outcomes related to use of the drug	1	2	3	4	5	6	7
☐	5. **Patient Considerations** ie. patient acceptance/ease of use/flavour of the drug	1	2	3	4	5	6	7
☐	6. **Economic Issues** ie. impact on total inpatient drug budget, past prescribing practices of physicians, patient mix that drug can be used for	1	2	3	4	5	6	7
☐	7. **Drug Handling Issues** ie. product stability/product storage issues, preparation requirements	1	2	3	4	5	6	7
☐	8. **Issues Related to the Organization** ie. organization goals, internal ability to evaluate studies, impact on other departments (financial, technical), is there a sponsor (internal champion) for the product, interaction amongst members of P & T Committee	1	2	3	4	5	6	7
☐	9. **Availability of Alternatives** ie. does this drug bring a therapeutic advantage over others, are alternatives (generics or different molecule) available	1	2	3	4	5	6	7
☐	10. **Post-decision Issues** ie. likelihood of drug being used as approved, or would its use grow beyond acceptable levels	1	2	3	4	5	6	7
☐	11. **Other External Considerations** ie. using the contents of the formulary in the education of care providers, customer service of supplier, whether the drug has been approved for use by the FDA/TPP	1	2	3	4	5	6	7

PLEASE COMPLETE NEXT PAGE

Factors that influence THE GROUP decisions

(✓) all that apply	Factor	Amount of Impact						
		Almost none	Hardly any	A little	Some	A fair bit	A lot	A great deal
☐	1. **Personal Interests** ie. personal financial motivation or other factors that benefit others	1	2	3	4	5	6	7
☐	2. **Pharmacologic Issues** ie. issues such as indications for use, toxicity, effectiveness, safety, adverse effects, drug interactions	1	2	3	4	5	6	7
☐	3. **Issues Related to the Use of the Drug in Hospital vs in the Community** ie. cost of drug in the community vs in hospital, drug usage patterns in community vs in hospital	1	2	3	4	5	6	7
☐	4. **Quality of Evidence Supporting the Drug Submission** ie. reliability/objectivity/credibility of the data available on the drug, care giver opinions regarding the drug, quality of documentation/literature review on the drug, patient outcomes related to use of the drug	1	2	3	4	5	6	7
☐	5. **Patient Considerations** ie. patient acceptance/ease of use/flavour of the drug	1	2	3	4	5	6	7
☐	6. **Economic Issues** ie. impact on total inpatient drug budget, past prescribing practices of physicians, patient mix that drug can be used for	1	2	3	4	5	6	7
☐	7. **Drug Handling Issues** ie. product stability/product storage issues, preparation requirements	1	2	3	4	5	6	7
☐	8. **Issues Related to the Organization** ie. organization goals, internal ability to evaluate studies, impact on other departments (financial, technical), is there a sponsor (internal champion) for the product, interaction amongst members of P & T Committee	1	2	3	4	5	6	7
☐	9. **Availability of Alternatives** ie. does this drug bring a therapeutic advantage over others, are alternatives (generics or different molecule) available	1	2	3	4	5	6	7
☐	10. **Post-decision Issues** ie. likelihood of drug being used as approved, or would its use grow beyond acceptable levels	1	2	3	4	5	6	7
☐	11. **Other External Considerations** ie. using the contents of the formulary in the education of care providers, customer service of supplier, whether the drug has been approved for use by the FDA/TPP	1	2	3	4	5	6	7

Which category below best describes you?

Administration Physician Pharmacist Nurse/Clinical Manager

Other (please specify)_____

Approximately what fraction of P & T committee meetings do you attend?

☐ 1/4 ☐ 1/2 ☐ 3/4 ☐ all

Please feel free to attach a list of other factors that you feel are important.

Appendix #3

Listing Status of Drug by RHA - 1996 Drugs (N = Not Listed, L = Listed)

Drug Brand Name	RHA A	RHA B	RHA C	RHA D	RHA E	RHA F	RHA G	RHA H1	RHA H2	RHA H3	RHA I1	RHA I2
Acel-P	N	N	N	N	N	N	N	N	L	N	N	N
Ambien	N	N	N	N	N	N	L	N	N	N	N	N
Clivarine	N	N	N	N	N	N	N	N	N	N	N	N
Dexferrum	L	L	N	N	N	N	L	N	N	N	N	N
Dynabac	N	N	N	N	N	N	N	N	N	N	N	N
Ethyol	N	N	N	N	N	N	N	N	N	N	N	N
Humalog	N	N	L	N	N	L	L	L	L	L	L	N
Infanrix	N	L	N	N	N	N	N	N	N	N	N	N
Invirase	L	N	N	N	N	N	N	N	N	N	N	N
Megalone	N	N	N	N	N	N	N	N	N	N	N	N
Merrem	N	N	N	N	N	N	N	N	N	N	N	N
Moru-Viraten Berna Vaccine	N	N	N	N	N	N	L	N	N	N	N	N
Naropin Injection	N	N	L	N	N	N	L	L	N	N	L	N
Nimbex Injection	N	N	N	N	N	N	N	N	N	N	N	N
Norprolac	N	N	N	N	N	N	N	N	N	N	N	N
Norvir	L	N	N	N	N	N	N	N	N	N	N	N
Panto-Byk	N	L	L	L	N	N	N	N	N	N	L	N
Redux	N	N	N	N	N	N	N	N	N	N	N	N
Reopro	N	N	N	N	N	N	N	N	N	N	N	N
Revex	N	N	N	N	N	N	N	N	N	N	N	N
Suprane	N	L	L	N	N	N	L	L	N	N	N	N
Trusopt	N	N	L	N	N	N	L	N	N	N	L	N
Ultiva Injection	N	L	N	N	L	N	N	N	N	N	N	N
Valtrex	N	N	N	N	N	N	N	N	N	N	L	N
Vexol	N	N	N	N	N	N	N	N	N	N	N	N
Zerit	L	N	N	N	N	N	N	N	N	N	N	N
Zyprexa tabs	N	L	L	N	L	L	L	N	N	N	L	L

Listing Status of Drug by RHA - 1997 Drugs (N = Not Listed, L = Listed)

Drug Brand Name	RHA A	RHA B	RHA C	RHA D	RHA E	RHA F	RHA G	RHA H1	RHA H2	RHA H3	RHA I1	RHA I2
Accolate	N	N	L	N	N	N	L	N	N	N	L	N
Agrylin Capsules	N	N	N	N	N	N	N	N	N	N	N	N
Allegra	N	N	N	N	N	N	L	N	N	N	L	N
Alphagan Ophtalmic Sol.	N	N	N	N	N	L	L	N	N	N	L	L
Anzemet	N	N	N	N	N	N	N	N	N	N	N	N
Aricept	N	N	L	N	N	L	N	N	N	N	N	N
Biltricide tabs	N	N	N	N	N	N	N	N	N	N	N	N
Bondronat	N	N	N	N	N	N	N	N	N	N	N	N
Cerebyx inject.	N	N	N	N	N	N	N	N	N	N	N	N
Cerezyme	N	N	N	N	N	N	N	N	N	N	N	N
Copaxone for Injection	N	N	N	N	N	N	N	N	N	N	N	N
Cytogam	N	N	N	N	N	N	N	N	N	N	N	N
Diovan caps	N	L	N	L	N	N	L	N	N	N	N	N
Dr. Scholl's Athlete's Foot Cream	N	N	N	N	N	N	N	N	N	N	N	N
Duratocin	N	L	N	N	N	N	N	N	N	N	L	N
Flolan for Injection	N	N	N	N	N	N	N	N	N	N	N	N
Foradil Dry Powder Capsules for Inhalation	N	N	N	N	N	N	N	N	N	N	N	N
Fraxiparine Injection	N	N	N	N	N	N	N	N	N	N	N	N
Gonal-F	N	N	N	N	N	N	N	N	N	N	N	N
Leucomax	N	N	N	N	N	N	N	N	N	N	N	N
Levaquin Tablets and Injection	N	N	N	N	L	N	L	L	L	N	L	N
Lipitor Tablets	L	L	L	N	L	L	L	N	N	N	N	N
Oxizole	N	N	N	N	N	N	N	N	N	N	N	N
Patanol	N	N	N	N	N	N	L	N	N	N	N	N
Puregon	N	N	N	N	N	N	N	N	N	N	N	N
Requip	N	N	N	N	N	N	N	N	N	N	N	N
Respigam	N	N	N	N	N	N	N	N	N	N	N	N
Rezulin	N	N	N	N	N	N	N	N	N	N	N	N
Seroquel Tablets	N	N	L	N	N	N	N	N	N	N	L	L
Skelid Tablet	N	N	N	N	N	N	N	N	N	N	N	N
Tasmar	N	N	N	N	N	N	N	N	N	N	N	N
Tazorac Gel	N	N	N	N	N	N	L	N	N	N	N	N
Topamax Tablets	L	N	N	N	N	N	N	N	N	N	N	N
Xalatan	N	N	N	N	N	N	L	N	N	N	L	L

Listing Status of Drug by RHA - 1998 Drugs (N = Not Listed, L = Listed)

Drug Brand Name	RHA A	RHA B	RHA C	RHA D	RHA E	RHA F	RHA G	RHA H1	RHA H2	RHA H3	RHA I1	RHA I2
Amerge	N	N	N	N	N	N	N	N	N	N	N	N
Atacand	N	L	N	N	N	N	N	N	N	N	L	N
Avapro	N	L	N	N	N	N	N	N	N	N	N	N
Azopt ophthalmic suspension	N	N	N	N	N	N	L	N	N	N	N	N
Baycol	N	N	N	N	N	L	L	N	N	N	N	N
Detrol	N	N	N	N	N	N	N	N	N	N	N	N
Emadine Ophthalmic Solution	N	N	N	N	N	N	N	N	N	N	N	N
Evista	N	N	N	N	N	N	N	N	N	N	N	N
Flomax	L	N	N	N	N	N	L	N	N	N	N	L
Glyset	N	N	N	N	N	N	N	N	N	N	N	N
Lymerix	N	N	N	N	N	N	N	N	N	N	N	N
Mirapex	N	N	N	N	N	N	N	N	N	N	N	N
Plavix	N	N	L	N	N	N	L	N	L	L	L	N
Raxar	N	N	N	N	N	N	N	N	N	N	N	N
Rebif	N	N	N	N	N	N	N	N	N	N	N	N
Regranex	N	N	N	N	N	N	N	N	N	N	N	N
Rescriptor	L	N	N	N	N	N	N	N	N	N	N	N
Singulair	N	N	N	N	N	N	L	N	N	N	L	N
Trovan (IV)	N	N	N	N	N	N	N	N	N	N	N	N
Trovan (Tablets)	N	N	N	N	N	N	N	N	N	N	N	N
Varivax	N	N	N	N	N	L	L	N	L	N	N	N
Viracept	L	N	N	N	N	N	N	N	N	N	N	N
Viramune	L	N	N	N	N	N	N	N	N	N	N	N
Wellbutrin SR	L	L	L	N	N	N	N	N	N	N	L	N
Zomig	N	N	N	N	N	N	N	N	N	N	N	N